BIOTECHNOLOGY AND ENVIRONMENTAL PROTECTION

PROGRAM PROFILE

Goal	To oversee the development and introduction of genetically engineered organisms and products, and the coordination of biotechnology policy in a manner that facilitates trade; assure environmental stewardship by monitoring impacts of APHIS programs; protect animal health by ensuring the purity, safety, potency, and efficacy of veterinary biological products; maintain registrations/approvals of chemicals used in APHIS programs, while helping the Agency identify emerging, less environmentally intrusive alternatives to current practices; track pesticide usage where needed for registration reporting; and achieve cost-effective compliance with environmental review and reporting requirements and incorporate a solid environmental ethic into Agency programs.
Enabling Legislation	Virus-Serum-Toxin Act of 1913 (21 USC 151-158); Federal Plant Pest Act of 1957 (7 USC 150aa-150jj); Plant Quarantine Act of 1912 (7 USC 151-164, 166, 167); Organic Act of 1944 (7 USC 147a); animal quarantine laws, particularly 21 USC 134-134h); 7 CFR 1b- Departmental requirements for National Environmental Policy Act (NEPA).
Economic Significance	This program's time-efficient, cost-effective notification procedures have removed the excessive regulatory burden on the biotechnology industry. This has led to a significantly greater volume of transgenic plants (some with value-added traits) that are coming to the marketplace after being safely tested in the field.
Principal Approach And Methods	Coordinates biotechnology regulatory activities within USDA and with other Federal agencies; liaison between public (State, Federal, international) and private organizations on matters and functions pertaining to regulation of agricultural biotechnology; evaluates requests and issues permits for field testing of genetically engineered plants or microorganisms. Through environmental analysis, development of survey and monitoring protocols, and residue testing,

creates a "circle of environmental protection" concept. Under this concept, Environmental Analysis & Documentation (EAD) unit works with planners to identify viable alternatives to current control/eradication practices; also documents APHIS' environmental planning activities. The Data Support Staff maintains registrations/approvals of chemicals used in APHIS control programs while helping to identify less environmentally invasive approaches. National Monitoring and Residue Analysis Laboratory (NMRAL) at Gulfport, MS, analyzes samples of soil, water, and crops for pesticide residue to determine safety of ongoing or alternative programs.

History

Due to rapid expansion of agricultural biotechnology in mid-1980s, need for well-defined regulatory structure became apparent to ensure safety in development. In response, APHIS requested funding in FY 1988 to establish regulatory program. The Agency has subsequently issued more than 1,000 permits for safe field testing of genetically modified plants and micro-organisms. These products represent millions of dollars in public and private investment, and the hope of more productive and environmentally benign approaches to agriculture. In FY 1992, APHIS consolidated its three environmental units (EAD, the Technical Services Staff, and NMRAL) under the biotechnology and environmental protection unit to integrate environmental planning into program development, promote exploration of alternatives to current control/eradication programs, and anticipate and prevent environmental problems.

State and Local Cooperation

APHIS works through State departments of Agriculture to ensure State authorities are informed of pending applications which may involve introduction of genetically engineered products within their borders. Views of State officials are solicited early in the application process and are an integral part of APHIS review process.

Involvement of Other Agencies

EPA, FDA, Fish and Wildlife Service.

RESOURCE DATA

----------Obligations----------

	Direct	Reimbursement	User Fees	Staff-Years
FY 1997	$7,978,018	--	--	122
FY 1998	$8,118,902	--	--	114
FY 1999	$7,401,956	--	--	101
FY 2000 (est.)	$8,523,000	--	--	111
FY 2001 (est.)	$10,283,000	--	--	117

	APHIS	Coop	Total	CCC	Contingency Fund
Cum.	$66,963,174	$1,899,504	$68,862,678	$2,238,000	--

RECENT ACCOMPLISHMENTS

Permits, Notifications, and Petitions

In FY 1999, the volume of transgenic plants tested in the field and entering the marketplace continued to increase. APHIS issued 1,264 movement notifications/permits and 1,010 release notifications/permits. In FY 1999, APHIS accepted comprehensive permits, which allow numerous requests--up to hundreds--on one permit. Also, biotechnology-derived products release site increased from 4,544 in FY 1998 to 5,259 in FY 1999. APHIS' streamlined, expedited notification procedures significantly increased field testing. APHIS was able to simplify regulatory requirements for certain field trials involving certain modified crops saving procedure time and money. APHIS was able to encourage innovative research and assure appropriate regulatory oversight at the same time. Since the program's inception in 1987, APHIS has regulated 54 field tests of genetically engineered crop varieties, with six new test occurring in FY 1999. Corn is the highest genetically engineered application.

APHIS determined non-regulated status for herbicide-tolerant soybean, beet, rapeseed, rice and corn crops, as well as insect/viral-resistant potato crops in FY 1999. Also, the Agency granted two extensions for existing non-regulated cropstatus; one for corn and the other for soybean. In addition, APHIS continued providing daily Internet updates on field testing and commercialization of new crop varieties. This information is frequently accessed by companies, individual researchers, and others who use this information to track the progress of emerging issues with agricultural biotechnology.

Harmonization of Regulations

APHIS continued to foster regulation harmonization for genetically-engineered plants and micro-organisms. Specifically, the Agency participated in United States/European Community bilateral environmental consultations and held frequent bilateral consultations with the European Commission and Member States. These consultations ensure that scientific issues are discussed and that trading partners understand APHIS' regulatory procedures. APHIS also held AgBiotech Bilaterals with Canada which have resulted in a Bilateral Agreement on molecular genetic characteristics of transgenic plants and future areas of cooperation. In cooperation with the Organization for Economic Cooperation and Development, APHIS developed regulatory documents concerning the testing and/or commercialization of genetically-engineered plants and micro-organisms. The Agency continued working with stakeholders to enhance the international harmonization of regulations. APHIS continues to sponsor additional biosafety workshops around the world. In FY 1999, APHIS representatives met regularly with representatives from Argentina, Australia, Brazil, Canada, France, Indonesia, India, Italy, Mexico, the Philippines, and Turkey to address safety issues regarding commodities that are under review, or have been approved. Also, APHIS participated in the U.S. delegation to the Biosafety Working Group to negotiate a Biosafety Protocol. APHIS and other Federal agencies are working toward the development of an international instrument to

reduce restrictions on the transboundary movement of organisms that pose no identifiable risks to biodiversity.

National Monitoring and Residue Analysis Laboratory (NMRAL)

NMRAL in Gulfport, Mississippi, continued supporting boll weevil, citrus canker, ALB, Oriental Fruit Fly, MFF, and Medfly programs in FY 1999. NMRAL provided sampling and analysis of worker exposure to chemicals both at the laboratory and at port facilities. NMRAL performed laboratory analysis for pesticide residues and for industrial chemicals, and analysis for pesticide residues in food commodities for the Agriculture Marketing Service's (AMS) Pesticide Data Program. NMRAL also provides pesticide testing work for the Asian Longhorned Beetle control program. In Addition, NMRAL analyzed tobacco samples for the Farm Service Agency (FSA) and soybeans for export for the AMS Commodity Certification Program.

NMRAL conducted 4,617 analysis in FY 1999, including 1,153 analysis in support of APHIS programs and 3,464 analysis on a reimbursable basis for other agencies. In addition, we conducted 1,470 quality control analysis to validate sample results.

In FY 1999, NMRAL conducted contract analysis for AMS, the FSA and the Boll Weevil Eradication Foundation (Southeast and Southwest). In FY 1999, NMRAL analyzed five commodities for AMS for benomyl and thiobendazole and analyzed Commodity Certification soybeans for six herbicides. In addition, NMRAL analyzed environmental impacts of insecticides used in the boll weevil eradication program.

Environmental Analysis and Documentation (EAD) and Data Support

The EAD Unit manages and coordinates the preparation of environmenal assessments (EA), environmental impact statements (EIS), environmental analyses, biological consultations, and related technical documents for APHIS programs. In FY 1999, EAD completed 34 EAs, 30 biological consultations, and 3 EIS', in compliance with the requirements of the National Environmental Policy Act and other Federal environmental laws, regulations, and executive orders.

EAD also completed numerous background documents, such as human health risk assessments and ecological risk assessments, to provide the required analysis in the environmental documents. To further APHIS' environmental ethic, EAD trained personnel on environmental laws, regulations and processes. EAD, in cooperation with Civil Rights Enforcement and Compliance (CREC), drafted an "Environmental Justice Strategy" and is currently preparing a pamphlet for issuance to Agency employees regarding the implementation of Executive Order 12898, "Environmental Justice." EAD participated in cooperative ventures that led to more efficient and effective use of government resources and expertise during FY 1999. EAD continued involvement with other agencies in discussions and negotiations on NAFTA issues, such as Transboundary Environmental Impact Assessment. Also, the Unit continued cooperation with the U.S. Department of Justice's Drug Enforcement Administration in preparing supplements to two EIS', and with EPA and the Office of Pest Management Policy (OPMP) on the malathion policy. In addition, EAD provided technical expertise for risk assessment work for FS, and for evaluating NAPIAP (National Agricultural Pesticide Impact Assessment Program) grant proposals for OPMP, and for reviewing a number of organic phosphate risk assessments.

The Data Support Team (DST) maintains pesticide registrations and drug approvals for products used in APHIS programs, as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The DST also helps the Agency identify emerging alternatives to products that are less environmentally invasive. In FY 1999, DST handled the following actions for pesticide and drug products: 18 Section 3 pesticide registrations, 1 Section 3 application resubmission, 16 Section 18 emergency exemptions to allow the unregistered use of a pesticide in a specific area for a limited time if emergency pest conditions exist), 5 Section 24(c) local needs State registrations for pesticides, 1 Section 25b product (exempt from registration, although State use may require approval by State lead agency), 3 Section 3 reregistration eligibility documents, and 4 investigational new animal

drugs. Each of these actions requires extensive supporting data and documentation regarding APHIS' use of a product. Besides maintaining the product registrations and approvals, the DST prepares quarterly reports on adverse effects incidents of APHIS registered products, as required by Section 6(a)(2) of FIFRA. In addition, the DST participated in the Rodenticide Stakeholder's Working Group to develop risk mitigation measures that will reduce the exposure of children to rodenticides. DST also worked with other APHIS program areas to amend and update the agency's pesticide applicators certification and training plan.